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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GREENBERG TRAURIG, LLP MET LIFE BUILDING 200 PARK AVENUE NEW YORK, NY 10166			COUGHLAN, PETER D	
			ART UNIT	PAPER NUMBER
			2129	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/542,208

Applicant(s)

BUSCEMA, MASSIMO

Examiner

Peter Coughlan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. Claims 1-34 are pending in this application.

Claim Objections

2. Claims 4-7, 10-14, 16-18, 20-23, 25-29, 31-34 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 4-7, 10-14, 16-18, 20-23, 25-29, 31-34 not been further treated on the merits.

35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-29 are rejected under 35 U.S.C. 101 for nonstatutory subject matter. The computer system must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77. The invention is ineligible because it has not been limited to a substantial practical application. Optimizing a database for training and testing purposes has no practical application. The result has to be a practical application. Please see the interim guidelines for examination of patent applications for patent subject matter eligibility published November 22, 2005 in the official gazette.

In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. The invention is to improve a training database of sample records. If said improved training database is not employed in some fashion then it is an exercise only and without practical application.

The invention must be for a practical application and either:

- 1) specify transforming (physical thing) or
- 2) have the FINAL RESULT (not the steps) achieve or produce a useful (specific, substantial, AND credible), concrete (substantially repeatable/ non-unpredictable), AND

tangible (real world/ non-abstract) result.

A claim that is so broad that it reads on both statutory and non-statutory subject matter, must be amended, and if the specification discloses a practical application but the claim is broader than the disclosure such that it does not require the practical application, then the claim must be amended.

Claims that recites the improvement of a training database or sample records without a real world application or function are not statutory.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. 'Structure of the training' could have numerous meanings but none within the specification.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. With the introduction of the number of variables along with the variables themselves introduces two independent domains of variables without a methodology on how to solve it.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "one to a following status level defined for this genes" in claim 19 is a relative term which renders the claim indefinite. The term "one to a following status level defined for this genes" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This is a variable and can not within a claim.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases 'a reduced number' and 'microarray' are not clearly defined nor an accepted term within the art.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word 'pseudo-random' is not clearly defined nor an accepted term within the art.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word 'close' is not clearly defined nor an accepted term within the art.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 8, 9, 19, 24 are rejected under 35 U.S.C. 102(e) (hereinafter referred to as **Lapointe**) being anticipated by Lapointe et al., U.S. 20030004906.

Claim 1

Lapointe anticipates defining a set of one or more distributions of the database records onto respective training and testing subsets (**Lapointe**, ¶0010; 'Distributions' of applicant is equivalent to 'sufficient training data' of Lapointe.) ; using the defined set of distributions to train and test a first generation set of one or more prediction algorithms and assigning a fitness score to each (**Lapointe**, ¶0066 and ¶0468; Each 'prediction algorithm' of applicant is equivalent to each node of the neural network. 'Fitness score' of applicant is equivalent to 'output' of Lapointe.); feeding the set of prediction algorithms to an evolutionary algorithm which generates a set of one or more second generation prediction algorithms and assigns a fitness score to each (**Lapointe**, ¶0468; 'Evolution algorithms' of applicant is equivalent to the algorithm that 'missing data was replaced' by Lapointe.); and continuing to feed each generational set of prediction algorithms to the evolutionary algorithm until a termination event occurs (**Lapointe**, ¶0469; 'Termination' of applicant occurs when the 'desired output would fall in the range of 0.0 to 1.0' of Lapointe.) where said termination event is at least one of a prediction algorithm is generated with a fitness score equaling or exceeding a defined minimum value (**Lapointe**, ¶0469; 'Minimum value' of applicant is equivalent to '0.0' of Lapointe.), the maximum fitness score of successive generational sets of prediction algorithms converging to a given value, and a certain number of generations having been

generated. (**Lapointe**, ¶0469; 'Maximum value' of applicant is equivalent to '1.0' of Lapointe.)

Claim 2

Lapointe anticipates generating a population of prediction algorithm each one of them is trained and tested according to a different distribution of the records of the data set in the complete database onto a training data set and a testing data set (**Lapointe**, ¶0007); each different distribution being created by a random or pseudo-random distribution (**Lapointe**, ¶0141); each prediction algorithm of the said population is trained according to its own distribution of records of the training set and is validated in a blind way according its own distribution on the testing set (**Lapointe**, ¶0141; 'Validated in a blind way' of applicant is accomplished by using 'random number seeds' of Lapointe.); a score reached by each prediction algorithm is calculated in the testing phase representing its fitness (**Lapointe**, ¶0760); an evolutionary algorithm being further provided which combines the different models of distribution of the records of the complete data set in a training and in a testing set which sets are represented each one by a corresponding prediction algorithm trained and tested on the basis of the said training and testing data set according to the fitness score calculated in the previous step for the corresponding prediction algorithm (**Lapointe**, ¶0007; 'Combines different models' of applicant is equivalent to 'training data' which is composed training examples' of Lapointe.); the fitness score of each prediction algorithm corresponding to one of the different distributions of the complete data set on the training and the testing

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data sets being the probability of evolution of each prediction algorithm or of each said distribution of the complete data set on the training and testing data sets. (**Lapointe**, ¶0760) Repeating the evolution of the prediction algorithm generation for a finite number of generations or till the output of the genetic algorithm converges to a best solution and/or till the fitness value of at least some prediction algorithm related to an associated data records distribution has reached a desired value; (**Lapointe**, ¶0125 and formula between ¶0125 and ¶0126; 'Finite number of generations' of applicant is illustrated by the values of the double summation symbols, '10' and 's' of Lapointe.) setting the data records distribution for the best solution as the optimized training and testing subsets for training and testing prediction algorithm. (**Lapointe**, ¶0012; 'Setting the data records' of applicant is equivalent to 'final diagnosis' of Lapointe.)

Claim 3

Lapointe anticipates to each record of the data set a distribution variable is associated which is binary and has at least two status, one of this two status being associated with the inclusion of the record in the training set and the other in the testing set. (**Lapointe**, ¶0010; Lapointe illustrates there exists training and testing data.)

Claim 8

Lapointe anticipates the different choices of the structure of the training and of the testing data subsets consist in different selections of the number of input variables of the data records of the database, which selections consist in leaving out at least one, preferably two or

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more variables from the entire input variable set forming each record, the records of the data base comprising a certain number of known input variables and a certain number of known output variables. (**Lapointe**, ¶0184; Lapointe illustrates withholding a variable in training runs.)

Claim 9

Lapointe anticipates defining a distribution of data from the complete data set onto a training and onto a testing data set (**Lapointe**, ¶0154); generating a population of different prediction algorithm each one having a training and/or testing data set in which only some variables have been considered among all the original variables provided in the data sets, each one of the prediction algorithm being generated by means of a different selection of variables. (**Lapointe**, ¶0066; Each 'prediction algorithm' of applicant is equivalent to each node of the neural network.) Carrying out learning and testing of each prediction algorithm of the population and evaluating the fitness score of each prediction algorithm (**Lapointe**, ¶0469; 'learning' of applicant is equivalent to 'reprocessed' of Lapointe.). Applying an evolutionary algorithm to the population of prediction algorithms for achieving new generations of prediction algorithm (**Lapointe**, ¶0468; 'Evolution algorithms' of applicant is equivalent to the algorithm that 'missing data was replaced' by Lapointe.); for each generation of new prediction algorithms representing each one a new different selection of input variable, the best prediction algorithm according to the best hypothesis of input variables selection is tested or validated. (**Lapointe**, ¶0036; If a variable improves the results then it is selected for the next generation of the prediction algorithm.) A fitness score is evaluated and the prediction

algorithms representing the selections of input variables which have the best testing performances and the minimum input variables are promoted for the processing of the new generations. (**Lapointe**, ¶0432)

Claim 19

Lapointe anticipates characterized in that genes rejection consist in modifying the status of the genes variable of the individuals from one to a following status level defined for this genes (variable). (**Lapointe**, ¶0034, the two status levels for genes are above average and below average.)

Claim 24

Lapointe anticipates a software program stored on a memory device, the said software program consisting in the method according to one or more of the preceding claims in the form of a executable instructions of a CPU or of a computer system. (**Lapointe**, ¶0006)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lapointe as set forth above, in view of Boden. (U. S. Patent 5708774, referred to as **Boden**)

Claim 15

Lapointe fails to particularly call for, coupling purposes and for generation of children, both parent individuals must have a fitness value close to the average health of the entire population.

Boden teaches that for coupling purposes and for generation of children, both parent individuals must have a fitness value close to the average health of the entire population. (**Boden**, C6:16-36; 'Close to the average' of applicant is equivalent to 'based on the fitness' of Boden.) It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to modify the teachings of Lapointe by using ranges within an average as taught by Boden to have coupling purposes and for generation of children both parent individuals must have a fitness value close to the average health of the entire population.

For the purpose of not using extreme cases when modifying the training base.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lapointe as set forth above, in view of Kwok. (U. S. Patent 6177249, referred to as **Kwok**)

Claim 30

Lapointe does not teach a microarray for genotyping operations, the said method comprising the steps of defining a certain number of theoretically relevant genes or alleles or polymorphisms considered relevant for a certain biologic condition like a tissue structure, a pathology or the potentiality of developing a pathology or an anatomic or morphologic feature; providing a database of experimentally determined data in which each record relates to a known clinical or experimental case of a sample population of cases and which records comprise a certain number of input variables corresponding to the presence/absence of a certain predetermined number of polymorphisms and/or mutations and/or equivalent genes of a certain number of theoretically probable relevant genes and one or more related output variables

corresponding to the certain biological or pathologic condition of the said clinical and experimental cases of the sample population.

Kwok teaches a microarray for genotyping operations (**Kwok**, abstract), the said method comprising the steps of defining a certain number of theoretically relevant genes or alleles or polymorphisms considered relevant for a certain biologic condition like a tissue structure, a pathology or the potentiality of developing a pathology or an anatomic or morphologic feature (**Kwok**, C4:19-32); providing a database of experimentally determined data in which each record relates to a known clinical or experimental case of a sample population of cases and which records comprise a certain number of input variables corresponding to the presence/absence of a certain predetermined number of polymorphisms and/or mutations and/or equivalent genes of a certain number of theoretically probable relevant genes and one or more related output variables corresponding to the certain biological or pathologic condition of the said clinical and experimental cases of the sample population. (**Kwok**, C16 through C19 tables 4 and 5; Kwok illustrate an example of a database of diallelic markers.) It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to modify the teachings of Lapointe by introducing using the invention for pathology purposes as taught by Kwok to have a microarray for genotyping operations, the said method comprising the steps of defining a certain number of theoretically relevant genes or alleles or polymorphisms considered relevant for a certain biologic condition like a tissue structure, a pathology or the potentiality of developing a pathology or an anatomic or morphologic feature; providing a database of experimentally

determined data in which each record relates to a known clinical or experimental case of a sample population of cases and which records comprise a certain number of input variables corresponding to the presence/absence of a certain predetermined number of polymorphisms and/or mutations and/or equivalent genes of a certain number of theoretically probable relevant genes and one or more related output variables corresponding to the certain biological or pathologic condition of the said clinical and experimental cases of the sample population.

For the purpose of implementing the invention is a real world application.

Lapointe teaches characterized by the following further steps determining a selection of a reduced number of the certain predetermined number of polymorphisms and/or genes by testing the association of the said genes or polymorphisms and the biological or pathological condition by means of mathematical tools applied to the database. (**Lapointe**, ¶0184; Lapointe illustrates withholding a variable in training runs.) The said mathematical tools comprise a so called prediction algorithm such as a so called neural network (**Lapointe**, ¶0468); and the further steps are carried out of dividing the database in a training and a testing dataset for training and testing the prediction algorithm (**Lapointe**, ¶0007); defining two or more different training dataset each one having records with a reduced number of the input variables which reduced number of input variables is obtained by excluding one or more input variables from the originally defined number of input variables, while for each record the reduced number of input variables of the corresponding training set has at least one input variable which is different from the input variables of the reduced number thereof of the other training

datasets, each different input variable consisting in a different gene or a different polymorphisms and/or a different mutation and/or a different functionally equivalent gene thereof of the originally considered genes or polymorphisms and/or mutations and/or functionally equivalent genes thereof considered theoretically potentially relevant for the biologic or pathologic condition (**Lapointe**, ¶0503; Lapointe illustrates having two sets of variables for 'endometriosis'.); training the prediction algorithm with each of the different training sets defined under point e) for generating a first population of different prediction algorithm which are divided into two groups of mother and father prediction algorithms and testing the said prediction algorithms with the associated testing set (**Lapointe**, ¶0007); calculating a fitness score or prediction accuracy of each father and mother prediction algorithms of the said first population by means of the testing results (**Lapointe**, ¶0468; 'Fitness score' of applicant s equivalent to 'output' of Lapointe.); providing a so called evolutionary algorithm such a genetic algorithm and applying the evolutionary algorithm to the first population of mother and father prediction algorithms for achieving new generation of prediction algorithms whose training and testing dataset comprises records whose input variables selections are a combination of the input variable selections of the records of the training and of the testing datasets of the first or previous population of father and mother prediction algorithms according to the rules of the evolutionary algorithm (**Lapointe**, ¶0468; 'Evolution algorithms' of applicant is equivalent to the algorithm that 'missing data was replaced' by Lapointe.); for each generation of new prediction algorithms representing each new variant selection of input variables, the best prediction algorithm according to the best hypothesis of input variable

selection is tested or validated by means of the testing dataset (**Lapointe**, ¶0036; If a variable improves the results then it is selected for the next generation of the prediction algorithm.); a fitness score is evaluated and the prediction algorithms representing the selections of input variables which have the best testing performance with the minimum number of input variables utilized are promoted for the processing of new generations (**Lapointe**, ¶0468); repeating the steps i) to k) until a predetermined fitness score defined as best fit of the prediction algorithm and a minimum number of input variables has been reached (**Lapointe**, ¶0526; Lapointe, demonstrates a repeating iteration for 'evaluation')

Lapointe does not teach defining as the selected relevant input variables i.e. as the relevant genes or polymorphisms and/or of mutations and/or of functionally equivalent genes thereof the ones related to the input variables of the selection represented by the prediction algorithm having both at least the predetermined fitness score and also the minimum number of selected input variables.

Kwok teaches defining as the selected relevant input variables i.e. as the relevant genes or polymorphisms and/or of mutations and/or of functionally equivalent genes thereof the ones related to the input variables of the selection represented by the prediction algorithm having both at least the predetermined fitness score and also the minimum number of selected input variables. (**Kwok**, C4:19-32) It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to modify the teachings of Lapointe by detecting and flagging input variables for pathological evaluations as taught by Kwok to define as the selected relevant input

variables i.e. as the relevant genes or polymorphisms and/or of mutations and/or of functionally equivalent genes thereof the ones related to the input variables of the selection represented by the prediction algorithm having both at least the predetermined fitness score and also the minimum number of selected input variables.

For the purpose of using the invention to detect possible harmful conditions before they become apparent by conventional means.

Conclusion

6. The prior art of record and not relied upon is considered pertinent to the applicant's disclosure.

-U. S. Patent Publication 20020077756: Arouh

-U. S. Patent Publication 20020016665: Ulyanov

-U. S. Patent 6035246: Wagner

-U. S. Patent 5832466: Feldgaer

-U. S. Patent 5761381: Arei

-U. S. Patent 5729623: Omatu

-‘Advanced training methods and new network topologies for hybrid MMI-connectionist/HMM speech recognition system’: Neukirchen

-‘Discriminative optimization of large vocabulary recognition systems’: Valtchev

-'Comparison of artificial neural network and Bayesian belief network in a computer-assisted diagnosis scheme for mammography': Zheng

-'An analytical approach to improving equipment productivity' DiSessa

-'Probability based optimization for network classifiers': Brauer

7. Claims 1-34 are rejected.

Correspondence Information

8. Any inquiry concerning this information or related to the subject disclosure should be directed to the Examiner Peter Coughlan, whose telephone number is (571) 272-5990. The Examiner can be reached on Monday through Friday from 7:15 a.m. to 3:45 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor David Vincent can be reached at (571) 272-3687. Any response to this office action should be mailed to:

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Peter Coughlan

9/12/2006



DAVID VINCENT
SUPERVISORY PATENT EXAMINER